UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MAX F. ROTHSCHILD, AMY L. VINCENT, CHRISTOPHER K. TUGGLE, CHRISTY GLADNEY, ALAN MILEHAM, OLWEN SOUTHWOOD, GRAHAM PLASTOW, and CAROLE SARGENT

Appeal No. 2005-1169
Application No. 09/900,063

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3, 8-11, 16, 17, 19, 20, 26-29, 36-38, 54 and 55.[1] Claims 1, 27, 36 and 54 are representative of the subject matter on appeal, and read as follows:

> 1. A method for screening animals to determine those more likely to produce larger litters comprising:
>
> obtaining a sample of genetic material from said animal;

[1] Claims 7, 14, 18, 30-34, 40, 41, 45 and 49 have been cancelled, and claims 4-6, 12, 13, 15, 21-25, 35, 39, 42-44, 46-48 and 50-53 stand withdrawn from consideration as being drawn to a nonelected group or species. See Appeal Brief, pages 2-3.

assaying for the presence of a genotype in the prolactin receptor gene sequence as set forth in SEQ ID NO: 3 or a region thereof in said sample, wherein said genotype is comprised of a polymorphism in the prolactin receptor gene associated with increased litter size; and

characterizing said animal.

27. A method for identifying a genetic marker for litter size in animals comprising the steps of:

breeding male and female animals of the same breed or breed cross or derived from similar genetic lineages;

determining the number of offspring produced by each female animal;

determining the polymorphism in the prolactin receptor gene as set forth in SEQ ID NO: 3 of each female animal; and

associating the number of offspring produced by each female animal with said polymorphism thereby identifying a polymorphism for pig[2] litter size.

36. A method for screening pigs to determine those more likely to produce larger litters, and/or those less likely to produce larger litters, which method comprises of the steps:

determining the alleles of prolactin receptor present in a pig having SEQ ID NO:3;

determining the alleles of other markers for genes known to affect litter size; and

selecting for animals with favorable combinations of alleles and against those carrying unfavorable combinations.

54. A method for identifying a marker correlated with litter size comprising the steps of:

obtaining a sample of genetic material from an animal, said sample comprising a prolactin receptor gene as set forth in SEQ ID NO:3;

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[2] The recitation of "pig" appears to lack antecedent basis in the claim, as the rest of the claim refers to "animal." Upon return of the application, the examiner should address this discrepancy in the claim.

assaying said prolactin receptor gene presented in said sample for a polymorphism;

correlating whether a statistically significant association exists between said polymorphism; and

litter size in an animal of a particular breed, strain, population, or group whereby said animal can be characterized for said marker.

The examiner relies upon the following reference:

Thisted, "What is a P-value?," Departments of Statistics and Health Studies, The University of Chicago, (http:/www.stat.uchicago.edu/~thisted), pp. 1-6 (1998)

Claims 1-3, 8-11, 16, 17, 19, 20, 26-29, 36-38, 54 and 55, all of the claims on appeal, stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., lack of adequate written description. The appealed claims also stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification is not enabling to practice the full scope of the invention. After careful review of the record and consideration of the issues before us, we affirm the written description rejection as to claims 1-3, 8-11, 16, 17, 19, 20, 26 and 36-38 and reverse as to claims 27-29, 54 and 55. With respect to the enablement rejection, we reverse the rejection with respect to claims 27-29, 54 and 55, but because we affirmed the written description rejection as to claims 1-3, 8-11, 16, 17, 19, 20, 26 and 36-38, we decline to reach the merits of the enablement rejection as to those claims.

DISCUSSION

Initially, we note that appellants argue that the claims do not stand or fall together, and set forth the subject matter of each claim. See Appeal Brief, pages 6-8. In argument, however, appellants only separately argue the patentability of the independent claims, i.e., claims 1, 27, 36 and 54. See id. at 12-13. We thus group the claims into four groups, with group I comprising claim 1 and the claims dependent thereon, i.e., claims 2, 3, 8-11, 16, 17, 19, 20 and 26; group II comprising claim 27 and the claims dependent thereon, i.e., claims 28 and 29; group III comprising claim 36 and the claims dependent thereon, i.e., claims 37 and 38; and group IV comprising claim 54 and the claims dependent thereon, i.e., claim 55. We thus focus our analysis on independent claims 1, 27, 36 and 54, with the dependent claims standing or falling with the claim on which they are dependent. See In re Dance, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998) (noting that dependent claims not argued separately on the merits rise or fall with the independent claim to which they relate); see also 37 CFR § 41.37(c)(1)(vii) ("A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.").

Claims 1-3, 8-11, 16, 17, 19, 20, 26-29, 36-38, 54 and 55, all of the claims on appeal, stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., for lack of adequate written description.

The Court of Appeals for the Federal Circuit, our reviewing court, has addressed the issue of what constitutes adequate written description for a claim drawn to a nucleic acid. In Enzo Biochem, Inc. v. Gen-Probe Inc, 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002), the court adopted a portion of the Guidelines proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

> The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics."

Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613 (citing Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description Requirement, 66 Fed. Reg. 1099, 1106 (January 5, 2001)).

The court also addressed the issue of what constitutes adequate written description of a claim to a broad genus of sequences. In The Regents of The University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the court determined that the disclosure of rat cDNA did not provide adequate written description support for claims drawn to mammalian and vertebrate DNA. Eli Lilly, 119 F.3d at 1567-68, 43 USPQ2d at 1405. The court stated:

> In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

In Enzo-Biochem, the court refined the approach advanced by Eli Lilly, adopting an example offered in the USPTO guidelines having facts that contrasted with those of Eli Lilly, wherein the written description requirement would be met. Thus, adequate written description may be present for a genus of nucleic acids based on their hybridization properties, "if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." Enzo Biochem, 323 F.3d at 967, 63 USPQ2d at 1615.

Claim 1 is drawn to a method of screening for animals that are more likely to produce large litters comprising the step of "assaying for the presence of a genotype in the prolactin receptor gene as set forth in SEQ ID NO:3 or a region thereof in said sample, wherein said genotype is comprised of a polymorphism in the prolactin receptor gene associated with increased litter size." Similarly, claim 36 is drawn to a method of screening for pigs that are more likely to produce a large litter, comprising the steps of "determining the alleles of prolactin receptor

present in a pig having SEQ ID NO: 3; determining the alleles of other markers for genes known to affect litter size; and selecting for animals with favorable combinations of alleles and against those carrying unfavorable combinations."

As noted by the examiner, claims 1 and 36 thus

> encompass a genus of nucleic acids which comprise prolactin receptor polymorphisms which are not disclosed in the specification. The genus includes an enormous number of polymorphisms for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named four polymorphisms for which data is provided demonstrating an association with the phenotypic trait, litter size. Thus, applicant has express possession of only four particular polymorphisms, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed which would permit selection of sequences as polymorphisms. . . . No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations of associating a polymorphism with litter size is provided. Further, these claims expressly encompass all the different possible allelic variants including insertions, deletion, substitutions and transversions at thousands of different sites. No written description of alleles, of upstream or downstream regions containing additional sequence, which are associated with any phenotype are described in the specification.

Examiner's Answer, pages 3-4. We agree with the examiner's analysis, and affirm the written description rejection as to claims 1-3, 8-11, 16, 17, 19, 20, 26 and 36-38.

Appellants argue that claim 1 contains a structural feature "by requiring that the genotype assayed for is variation present in the prolactin receptor gene as set forth in, or therein, of SEQ ID NO: 3." Appeal Brief, page 12. Appellants argue further that the claim requires a particular function by requiring "that the screened animal's prolactin receptor gene variant is associated with an

increased litter size." Id. Appellants conclude that "[t]he claim thereby recites a structural feature which is common to all members of the genus (a specific region of a DNA sequence) and additionally requires a particular function (causes a phenotypic difference in litter size)." Id.

Appellants argue similarly for claim 36 that it contains "the necessary structural feature by requiring that the alleles which are to be determined in said animal are contained within the prolactin receptor gene of SEQ ID NO: 3," and "also requires a particular function in that the alleles to be determined are to be associated with litter size." Id.

First, as noted by the examiner, the specification fails to disclose a representative number of species of polymorphisms present in SEQ ID NO: 3 that are associated with litter size. See Examiner's Answer, page 10. At best, appellants have disclosed three polymorphisms that may be correlated to litter size, see Appeal Brief, page 13, whereas claims 1 and 36 encompass any polymorphism that may be correlated to litter size.

Second, as also noted by the examiner, while the polymorphisms occur in SEQ ID NO: 3, the polymorphisms that are disclosed by the specification to be associated with litter size have no common structural element. See Examiner's Answer, pages 12-13.

Third, claims 1 and 54 are not limited to pigs. The polymorphisms disclosed in the specification have only been correlated to litter size in pigs. Thus, the specification fails to provide adequate written description for the method of claims 1 and 54, which encompass any polymorphism that may occur in SEQ ID NO: 3 that may be correlated to litter size in any mammal.

Appellants assert moreover that they have disclosed "at least" three polymorphisms that may be correlated to litter size. Appeal Brief, page 13. Appellants argue further that the specification discloses how the skilled artisan may identify polymorphisms within the prolactin gene set forth in SEQ ID NO: 3. See id. Finally, appellants contend that "[w]hile every polymorphism present in the [prolactin receptor] gene may not be associated with an increase in litter size, this does not negate written description as there is ample description of how to locate polymorphisms and how to correlate them to phenotypic traits." Id. at 14.

Appellants' argument that the specification teaches one skilled in the art to locate polymorphisms and correlate them to a phenotypic trait such as litter size relates to enablement, and not written description. And as noted by the Court of Appeals for the Federal Circuit, the written description requirement under 35 U.S.C. § 112, first paragraph, is separate and distinct from the enablement requirement. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991).

Claims 27 and 54, however, are drawn to methods for identifying a marker correlated with litter size. The examiner does not address in the rejection how such screening methods to identify a polymorphism associated with litter size are not supported by an adequate written description, and we are thus compelled to reverse the written description rejection as to claims 27 and 54 and the claims dependent thereon, i.e., claims 28, 29 and 55.

Claims 1-3, 8-11, 16, 17, 19, 20, 26-29, 36-38, 54 and 55 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification, while being enabling for some polymorphisms in the porcine prolactin receptor such as the Alu polymorphism, does not reasonably provide enablement for all polymorphisms including the MseI polymorphism.

The examiner states in the conclusion to the rejection, "the specification does not provide guidance to overcome art and specification recognized problems in the use of polymorphisms as prognostic of litter size as broadly claimed." Examiner's Answer, page 9 (emphasis in original). As we have noted above, the examiner has focused the rejection on the subject matter of claims 1 and 36 and the claims dependent thereon.

Therefore, as the examiner has not addressed the subject matter of claims 27, 28, 29, 54 and 55, i.e., methods for identifying genetic markers associated with litter size, we are compelled to reverse the enablement rejection as to those claims. Moreover, because we affirmed the written description

rejection of claims 1-3, 8-11, 16, 17, 19, 20, 26 and 36-38 above, we decline to reach the merits of the enablement rejection as to those claims.

CONCLUSION

The written description rejection as to claims 1-3, 8-11, 16, 17, 19, 20, 26 and 36-38 is affirmed, but is reversed as to claims 27-29, 54 and 55. With respect to the enablement rejection, it is reversed with respect to claims 27-29, 54 and 55, but because the written description rejection as to claims 1-3, 8-11, 16, 17, 19, 20, 26 and 36-38 was affirmed, we decline to reach the merits of the enablement rejection as to those claims.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART; REVERSED-IN-PART

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